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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,362	10/15/2004	Perry J Blackshear	4239-64828-02	3754

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EXAMINER	
NGUYEN, QUANG	

ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
10/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,362	BLACKSHEAR ET AL.	
	Examiner	Art Unit	
	Quang Nguyen, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 7/16/07.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 2-31,33-41,43-46,49-59 and 61-64 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 2-31, 33-41, 43-46, 49-59 and 61-64 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment filed on 7/16/07 was entered.

Amended claims 2-31, 33-41, 43-46, 49-59 and 61-64 are pending in the present application. In light of Applicant's amendment filed on 7/16/07, the following revised restriction is required.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group Restriction

Group I, claims 2-4, 14, 22-24, and 58, drawn to a substantially purified RFX4_v3 polypeptide and a method for screening compounds for the ability to alter RFX4_v3 activity using the same.

Group II, claims 5-13, 15-21, 25-27, drawn to an isolated nucleic acid molecule encoding a RFX4_v3 polypeptide, a vector, a host cell comprising the same and a method for producing a variant polypeptide using the same.

Group III, claims 28-30, drawn to a method for detecting a nucleic acid molecule in a biological sample.

Group IV, claims 31, 33-35, 40-41 and 44-45, drawn to a method for identifying a subject at risk of developing RFX4_v3 linked hydrocephalus by detecting in the subject a mutation in a RFX4_v3 nucleotide sequence, and a kit comprising a nucleic acid probe that specifically detects a mutation in a RFX4_v3 allele.

Group V, claims 31, 36-41, 43-44, 46 and 49, drawn to a method for identifying a subject at risk of developing RFX4_v3 linked hydrocephalus by detecting in the subject a mutation in a RFX4_v3 polypeptide, and a kit comprising an antibody that specifically

binds and detects a mutation in the protein expressed by a mutated RFX4_v3 allele; and an antibody that specifically binds to a substantially purified RFX4_v3 polypeptide.

Group VI, claims 50-57, drawn to a method for generating a non-human transgenic animal with a knockout for the RFX4_v3 gene, and a transgenic mouse whose somatic and germ cells comprise a disrupted endogenous RFX4_v3 gene.

Group VII, claims 59 and 61-62, drawn to a pharmaceutical composition comprising a therapeutically effective amount of RFX4_v3 polypeptide, variant or portion thereof and a pharmaceutically acceptable carrier, and a method of treating congenital hydrocephalus in a subject using the same pharmaceutical composition.

Group VIII, claims 59, 61 and 63-64, drawn to a pharmaceutical composition comprising a therapeutically effective amount of a nucleic acid sequence encoding a RFX4_v3 polypeptide, variant or portion thereof and a pharmaceutically acceptable carrier, and a method of treating congenital hydrocephalus in a subject using the same pharmaceutical composition.

The currently claimed subject matter, Inventions of Groups I-VIII, lacks unity of invention according to Rule 13.1 PCT for the following reasons.

The substantially purified RFX4_v3 polypeptide of Group I, the isolated nucleic acid molecule of Group II, the antibody that specifically binds and detects a mutation in a RFX4_v3 polypeptide or an antibody that binds to a RFX4_v3 polypeptide in Group V, a transgenic mouse of Group VI, a pharmaceutical composition comprising a therapeutically effective amount of a RFX4_v3 polypeptide of Group VII, and a pharmaceutical composition comprising a therapeutically effective amount of a nucleic acid sequence encoding a RFX4_v3 polypeptide of Group VIII are compositions that are different chemically one from the others, as well as each composition has different properties and/or characteristics one from the others. For examples, the polypeptide of Group I is made up of amino acid residues and different in the primary sequence from

the antibody of Group V. The isolated nucleic acid molecule of Group II is made up of nucleotides. The transgenic mouse of Group VI is a living entity, physically and chemically different from the other compositions. The pharmaceutical compositions of Groups VII and VIII are different chemically one from the other, as well as they have different components (e.g., a pharmaceutically acceptable carrier) and unlike other compositions they have pharmaceutical properties. **Therefore, each of the above compositions does not share the same technical feature, and accordingly the compositions lack the same or corresponding special technical features.**

The methods in Groups I-VIII are different one from the others by having different starting materials, different method steps and different desired end-results. For examples, **the first method of use** in Group I is directed to a screening method for one or more test compounds; **the first method of use** in Group II is drawn to a method for producing a variant polypeptide of the present invention involving the step of mutagenizing a wild type nucleic acid sequence; the method in Group III is for detecting a nucleic acid molecule in a biological sample; the method of Group IV is for detecting in the subject a mutation in a RFX4_v3 nucleotide sequence; the method of Group V is for detecting in the subject a mutation in a RFX4_v3 polypeptide; the method of Group VI is for generating a non-human transgenic animal with a knockout for the a RFX4_v3 gene; the methods in Groups VII and VIII are methods for treating congenital hydrocephalus using a therapeutically effective amount of RFX4_v3 polypeptide and a nucleic acid encoding the same, respectively. **Each different method step can be**

considered to be a "special technical feature"; and therefore the methods listed in Groups I-VIII lack the same or corresponding special technical features.

Because the currently claimed subject matter lacks unity according to Rule 13.1 PCT for the reasons set forth above, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Species Restriction

Should Applicants elect anyone of Groups I-VIII, this application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. **It has also been decided that, due to the high burden on the Office to search sequences ONE sequence constitutes a reasonable number for examination purposes**. The search of no more than one selected sequences may include the complements of the selected sequence and where appropriate, may include subsequences within the selected sequence (e.g., oligomeric probes and/or primers).

The species are as follows:

1. ***SEQ ID NO:8 (corresponding nucleic acid SEQ ID NO:37); SEQ ID NO:6 (corresponding nucleic acid SEQ ID NO:38) and SEQ ID NO:10 (corresponding nucleic acid SEQ ID NO:39).***
2. ***A single species of promoter recited in the Markush group of claim 10.***
3. ***A single species recited in the Markush group of claim 24.***

Applicant is required, in reply to this action, **to elect a single species consistent to the elected invention** to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

1. Each of the listed species of RFX4_v3 polypeptide or its corresponding encoded nucleic acid molecule with the specific recited SEQ ID No. is different physically and structurally one from the others.

2. Each of the listed species of a promoter with a specific recited SEQ ID No. is different chemically and structurally one from the other.

3. Each of the listed species of amino acid residues with a specific recited SEQ ID No. is different structurally and physically one from the others.

Each of the aforementioned species is different structurally one from the others. **Each different structure can be considered to be a "special technical feature"; and therefore the listed species lack the same or corresponding special technical features.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's SPE, Joseph T. Woitach, Ph.D., may be reached at (571) 272-0739.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has

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QUANG NGUYEN, PH.D.
PRIMARY EXAMINER